

## OTC Drug Marketing – Global Trends and Indian Experiences

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“Collaboration with civil society is no more a choice for corporates”

- Prof. C. K. Prahalad

“Involving society in the learning process is what we should look forward to”

- Prof. Yash Pal

Purchase and use of OTC drugs without full knowledge is not only a waste of resources for all stakeholders but can be harmful for consumers. Creating awareness of rational drug use is only possible through continued public education with a broad vision of good health and wellbeing of the society. In developed economies, the four As of marketing has been addressed fairly well but in India, the accessibility and awareness is still on a lower side especially for allopathic OTC drugs.

**Key Words:** Over the Counter (OTC) drugs, Pharmaceutical company, Continuous pharmacist education (CPE), Corporate Social Opportunity (CSO), Food and drug administration (FDA), Corporate social responsibility (CSR), Bottom of pyramid (BOP)

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### Introduction

This paper takes a look at the OTC drug marketing at a global level with special focus on US and Indian markets. The first section deals with changing consumer and his environment which is followed by a brief introduction to OTC segment. The second section gives an idea of the recent trends in United States OTC drug market followed by Europe and India. Section three deals with a small pilot study done by the author and the last section gives the holistic approach which Indian OTC drug marketing firms can adopt to create awareness about health and wellbeing.

### The changing consumer

The consumers are changing world over. Today they are more informed, use more gadgets, lead a fast life and there by face higher stress. Environmental changes in the form of ever increasing pollution, heavy road traffic leading to increasing commuting time, stressful workplace environment and fast changing technology put continuous pressure to adapt and adjust Changing lifestyle with smaller living space, less exercise (sedentary jobs), taking junk food, consuming addictive products to stay awake on the job for longer hours and eating on the run put more stress on the body which get expressed in the form of psychosomatic disorders like frequent headache, allergy, common cold, constipation, backache, acidity, chronic fatigue etc... which they are trying to manage with Over The Counter (OTC) drugs.

This has lead to steady increase in self medication for the past many years. The enfranchised customer of today feels more independent and self reliant and is hesitant to adopt the orthodox model of expert prescription, monitored medication and supervision throughout the treatment period to manage common ailments. With increasing medico legal cases, Doctors are also not ready to take any risk and insist on detailed investigation to diagnose even a common ailment. This adds to the already existing high cost of following an orthodox model.

Most of the OTC drugs are safe, effective, economical and since it is available with out a prescription, the perceived value of OTC medication is higher compared to orthodox model for common ailments.

Self-administration of treatment with over-the-counter drugs relies on the patient's judgment, supplemented by the information on the label, for correct diagnosis of the disorder or symptom. An incorrect diagnosis may lead to the use of an over-the-counter drug that has no efficacy in treating the actual condition present. In general, the dangers of misdiagnosis involve both the potential adverse effects of the drug when inappropriately used and the risks associated with lack of treatment for the actual cause of the symptoms.

**Table 1.** Benefits and risks of switching from prescription only to OTC**Possible benefits**

1. Increased access
2. Decreased frequency of visits to physicians, leading to lower healthcare costs
3. Improved education of consumers
4. Increased autonomy of patients
5. Decreased cost to third party players

**Possible risks**

1. Inaccurate diagnosis
2. Delay in obtaining needed therapy
3. Use of suboptimal therapy
4. Drug resistance
5. Increased costs to patients
6. Failure to follow label instructions (Adverse effects, Drug interactions)
7. Perceived loss of control by physicians

**The OTC Market**

Global OTC pharmaceuticals grew with CAGR of 5.1% for the five year period spanning 2002-06 to reach \$88.7 billion. At a global level pharma giants are leveraging the power of OTC to face the challenges they face today. Globalization, shrinking new product pipeline, increasing cost of new drug discovery, shrinking PLC of existing products, ever increasing demand by managed healthcare organisations, public and government to cut down the prices of patent protected drugs, stringent safety rules of FDA and entry of new players in the market are putting tremendous pressure on all pharma companies especially the giants. Pfizer Inc's, world's largest drug maker, recent decision to cut US sales force by about 20% clearly express the pressure such giants face.

**US OTC Pharmaceuticals market**

Approval of over-the-counter status for a drug requires an assessment by the Food and Drug Administration (FDA) that the drug is safe and effective.

Under current regulations, a new drug can be exempted from prescription-only status by FDA approval of a new-drug application supporting the use of the product on an over-the-counter basis. Alternatively, a drug can be marketed over the counter if its ingredients are included in previously published regulations defining the requirements for over-the-counter status and if the labeling of the product complies with these regulations. The standards also apply to drugs that have already been approved for prescription-only sale and that are being considered for a switch to over-the-counter status. The Drug Price Competition and Patent Term Restoration Act of 1984 potentially provides three additional years of marketing exclusivity for the makers of drugs switched from prescription to over-the-counter status if the FDA has required additional clinical trials deemed essential to evaluate the switch. If a prescription drug is approved for over-the-counter marketing, the drug may still be available by prescription for certain indications or for use at doses not approved for over-the-counter marketing.

The Durham–Humphrey and Kefauver–Harris Amendments define criteria to be used by the FDA in evaluating a new-drug application for a proposed over-the-counter drug. The required demonstrations of safety and efficacy for an over-the-counter drug include components distinct from those for prescription drugs.

1. Can the patient recognize and diagnose in himself or herself the condition specified in the proposed indication?
2. When reading a product label, can the patient extract the key information necessary to use the drug properly?
3. Will the over-the-counter drug be effective when used as recommended?
4. Is the drug safe when used as instructed?

The US OTC Pharmaceuticals market generated total revenues of \$21.2 billion in 2006, this representing a CAGR of 4.3% for the five year period spanning 2002-06. In comparison, the Chinese and Japanese OTC Pharmaceuticals markets grew with CAGRs of 7% and 2.9% over the same period, to reach respective values of \$11.9 billion and \$14.8 billion in 2006.

**Table 2. United States OTC pharmaceuticals market segmentation: % share, by value, 2006\*\***

Category	% share
Cough and cold preparations	22.30
Vitamins and minerals	18.70
Analgesics	15.20
Medicated skin products	12.60
Traditional medicines	5.30
Other	25.90

**Table 3. United States OTC pharmaceuticals market Share: % share, by value, 2004\*\***

Company	% share
Pfizer Inc	7.20
Wyeth	6.00
Johnson & Johnson	4.40
Other	82.40

**Table 4. United States OTC pharmaceuticals distribution: % share, by value, 2004\*\***

Channel	% share
Pharmacies / drugstores	32.30
Mass merchandisers / warehouse clubs	20.80
Supermarkets/hypermarkets	8.60
Other	38.30

The trend in US market is to convert prescription drugs into OTC at the end of patent protection (switch) so that there is continued revenue flow from the product. Since many pharma companies do not have any experience in using mass media and also have smaller distribution network compared to FMCG giants to do mass marketing, they are partnering with them to do the same. Successful launch of Prilosec OTC (Omeprazole of AstraZeneca for frequent heartburn) by P&G in 2003 is a classic example. The switch to OTC is done in a total or partial way. Under partial switch the molecule will enjoy dual regulatory status-low dose as OTC and higher dose is dispensed by the pharmacist only on prescription.

### European OTC Pharmaceuticals market

The European OTC Pharmaceuticals market generated total revenues of \$23.6 billion in 2006, this representing a CAGR of 2.5% for the five year period spanning 2002-06. In comparison, the Global and Asia-Pacific OTC Pharmaceuticals markets grew with CAGR of 5.1% and 6.9% over the same period, to reach respective values of \$88.7 billion and \$39.1 billion in 2006.

**Table 5. Europe OTC pharmaceuticals market segmentation : % share, by value, 2006\*\***

Category	% share
Cough and cold preparations	18.70
Traditional medicines	16.70
Vitamins and minerals	16.00
Analgesics	15.00
Medicated skin products	8.90
Other	24.60

**Table 6. Europe OTC pharmaceuticals market Share:% share ,by value, 2004\*\***

Company	% share
Sanofi-Aventis	7.10
Pfizer Inc	5.40
GSK	4.50
Other	83.00

**Table 7. Europe OTC pharmaceuticals distribution:% share ,by value, 2004\*\***

Channel	% share
Pharmacies / drugstores	88.00
Specialist retailers	7.30
Supermarkets/hypermarkets	2.40
Other	2.20

**Indian OTC Pharmaceuticals market**

Indian market faces the problem of ‘Deemed OTC market’ where in ethical drugs are also sold without a prescription due to poor monitoring and control by FDA. Self medication tendency is traditionally very high due to the high availability of traditional medicines, the awareness and acceptance of which is very high among the public.

The Indian OTC pharmaceuticals market generated total revenues of \$2.5 billion in 2006, this representing a compound annual growth rate of 8.3% for the five year period spanning 2002-2006.

In comparison ,the US and Chinese OTC pharmaceuticals markets grew with CAGRs of 4.3% and 7% over the same period ,to reach respective values of \$21.2billion and \$11.9billion in 2006. Traditional medicines proved the most lucrative for the Indian OTC pharmaceuticals market in 2006, generating total revenues of \$679.3 million. In comparison, sales of cough and cold preparations generated revenues of \$492.6 million in 2006.

**Table 8. Indian OTC pharmaceuticals market segmentation: % share, by value, 2006\*\***

Category	% share
Traditional medicines	27.30
Cough and cold preparations	19.80
Vitamins and minerals	11.60
Analgesics	11.40
Medicated skin products	2.60
Other	27.30

**Table 9. Indian OTC pharmaceuticals market Share: % share, by value, 2004\*\***

Company	% share
Pfizer Inc	5.10
Sanofi-Aventis	5.00
Johnson & Johnson	4.80
Other	85.10

**Table 10. Indian OTC pharmaceuticals distribution: % share, by value, 2004\*\***

Channel	% share
Pharmacies/drugstores	73.60
Supermarkets/hypermarkets	12.60
Specialist retailers	12.50
Other	1.40

Only 35 % of the population has access to allopathic drugs. There is a need to create an infrastructure which will guarantee both access to medicines and provide medical support for the poor. There is an urgent need to design interventions to modify the behaviour of every one

involved in the pharmaceutical supply chain (Producers, providers, retailers, consumers and Govt.) in order to duce over prescribing and the inappropriate drug use ,and rationalize health expenditures.

Currently, non pharmacy stores can sell a few drugs on the Schedule K (Old and safer) of the Drugs & Cosmetics Act in rural areas in villages whose population is below 1,000. Recent government plan to make available Schedule K drugs also through grocery shops, supermarkets, department stores etc.. has met with high resistance from 8 lakh chemists of India. With grocery stores having 52% reach in Indian market, the highest compared to any other store, the Government's plan to make OTC more accessible is highly appreciable.

### The Study

A pilot study was done by the author to understand the awareness, attitude and usage of OTC drugs among adults in the National Capital Region. A sample of 50 respondents was selected using convenience and judgmental sampling which included people of both sexes with different socio economic background. Data was collected using a structured questionnaire. The response from this study is shown in Table 11.

**Table 11. Demographic profile ( Total sample = 50 adults )**

S.No	Parameter		Frequency	%
1	Gender	Male	25	50
		Female	25	50
2	Education	Graduate	25	50
		Postgraduate	25	50
3	Age group (Years)	20-30	36	72
		31-40	10	20
		41-50	4	8

#### Summary of responses

S.No	Parameter	Response	Frequency	%
1	Safe to buy and use	Yes	46	92
		No	4	8
2	Common ailments	Headache	43	16
		Common cold	40	15
		Fever	38	15
		Acidity	33	13
		Cough	31	12
		Body pain	30	11
		Stomach ache	15	6
		Diarrhoea	14	5
		Allergy	12	5
		Flu	6	2
3	Usage in Children below 10 years	Yes	6	12
		No	44	88
4	Encourage others to take OTC	Yes	16	32
		No	34	68
5	Seek more information from chemist	Yes	26	52
		No	24	48
6	Awareness of side effects	Yes	25	50
		No	25	50
7	Availability through Non-chemist outlets	Yes	22	44
		No	28	56
8	Maintain stock of OTC at home	Yes	44	88

		No	6	12
9	Insist on same brand	Yes	20	40
		No	30	60
10	Is self medication increasing in society	Yes	42	84
		No	8	16
	Preferred medium for receiving information on			
11	rational use of drugs	Print	39	38
		TV	32	31
		Internet	20	19
		Radio	9	9
		Mobile	4	4

The awareness level about OTC as a category was high and is considered to be safe, on an average each person suffered from more than five common ailments for which he used OTC drugs, 50% of respondents did not know the side effects of the OTC drug they take, 84% of respondents believe that self medication with OTC drugs is increasing in the society and they prefer print and TV as the main medium to receive information on rational use of drugs from pharmaceutical companies.

### Go beyond Accessibility

Any society will be judged by its ability to provide universal healthcare for its people. This does not merely entail the ability to treat diseases and ailments but also to prevent their onset by means of suitable systems and measures.

The rich at least have access to information about health related issues. That is not the case with the many lower income groups and poorer people. There is a total absence of health awareness among these sections. And even if they want to, many of them cannot afford a visit to a doctor, or afford regular medication when it is urgently required. More often than not, they end up relying on quacks, thus the need for empowering them through health education for self management of common ailments to start of and finally to prevent common ailments.

The other reason being the less number of doctors in rural areas. Of the 6.5 lakh qualifies doctors, four fifth live in towns and cities. That leaves just 20% of the total medical community to take care of 76% of country's population.

The BOP is engaged in jobs which leave it confronted with constant insecurity about making ends meet .This majority does not have economic surplus and has just enough for covering its bare necessities. Investment in healthcare (read insurance) is an impossible luxury.

Advancement in the field of pharmaceutical research has deepened our understanding of diseases and its preventive measures but it has not percolated down. The information asymmetry is very high which escalate the medical care cost by late detection which demands urgent and costly interventions at tertiary care level. Diffusion of information will take time. The incidence of new cases of Polio at the end of 11 years of massive all India campaign is a classic example. This throws light on the urgent need to create health awareness with special focus on BOP and the development of a marketing model where there is continuous knowledge dissemination about disease prevention and management by rational use of drugs to doctors, Pharmacists, Nurses and patients simultaneously and is an urgent need and a big Corporate Social Opportunity.

A TIFAC (Technology, Information, Forecasting and Assessment Council) survey of the future scenario of Indian Epidemiology as perceived by medical practitioners reflect the reality that India would have the diseases of the developing world as well as the diseases of the developed world .

Health education programs need to be undertaken for specific target groups .Many NGOs and youth organizations can be fruitfully pooled in to fulfill major life saving missions. The TV and film media could also be tapped to spread the message, and there could be corporate sponsorship

for such programs. One of the main options available for India to contain the AIDS epidemic lies in creating community awareness about the disease.

We need to think holistically and innovatively and also understand the importance of interlinkages. Indian Pharmaceutical companies have a unique opportunity to take leadership in designing a consumer centric offering with high emphasis on consumer education and there by his empowerment.

This is the right time when Indian pharma companies should fulfill their duty of filling the existing gap in knowledge among public about the diseases they are trying to address with the company's OTC products. The opposition from the chemists can be managed by pharma companies by involving them as a key partner in this service. Offering a drug as OTC without educating the potential customers of its effective use will be self defeating. Thus by adding this service component (knowledge of ailment and how to treat) to the product (OTC Drug), the customers will derive superior value from the offer and the offering will become more acceptable for the public.

To achieve this win-win situation, the companies will have to focus on packaging (multilingual and in simple language), continuous pharmacist education (CPE) through training sessions, seminars, conferences etc... as is done for doctors and extensive use of communication (above-the-line and below-the-line) with the customers. Online media can be used but will be less effective since internet penetration is low. Compared to above-the-line, below-the-line is better for Indian market (multi lingual) since it can be more customized and is less costly. Pharma companies should jump at the Corporate Social Opportunity (CSO) which Indian market is offering. Government has taken the initiative to empower the customers by planning to make OTC drugs available through grocery stores. Improved access, continuous training of pharmacists, proper labeling and packaging, lower cost of OTC drugs and educating the customers of proper selection and use of OTC drugs is what Govt. and pharma companies should together ensure to empower pharmacists and customers to manage common ailments through OTC medication. With all leading pharma companies launching their public education campaigns to fill the knowledge gap in proper selection and use of OTC drugs, it can be a classic case of PPP where the ultimate winner will be the consumer.

### **The key players in the proposed new model**

The new proposed model of OTC drug marketing which is consumer education centric will involve FMCG firms, advertising and media firms, nurses, NGOs and pharmacists as important partners.

To communicate to more than 50 crore customers, pharma companies can take the assistance of advertising agencies and media firms and can monitor and control this with the help of the field force. Corporate hospitals can be of great help to pharma companies since most of them are already having patient clubs which organize education programmes. By sponsoring such clubs, the companies can partner in hospital's initiative and add more value in a very cost effective way. Thus hospitals and pharmacists can play the role of key partners in this initiative by pharma companies. Patient clubs can also be initiated with the help of pharmacists and this will give a superior role to him as an educator and counselor. The assistance of Diagnostic labs and the paramedical staff employed there can be sought.

To address the issue of accessibility the pharma companies can partner with FMCG companies and organized retailers. The organized retailer Subhiksha apart from opening pharmacy counters in all their outlets is also giving 10% discount on every purchase of any value.

Continuous education to public on diseases, its management and ultimately its prevention by pharma companies being in tune with their core business will be an act of CSR in alignment with company's value chain which is being recommended as the best way to involve in CSR by strategy guru M.E.Porter.

“Successful companies ,brands, products and so on ,have one common denominator, namely that they all succeed meeting not only the needs and wants of the customers ,but also succeed meeting the needs and wants of the ultimate consumer.”(Svensson,2001).The proposed new model can effectively address the accessibility and awareness aspects which will in turn increase the acceptance of OTC allopathic drugs and its rational use.

### **Conclusion**

In the OTC drug marketing, the Customer and Consumer being the same, companies have to immediately address the information needs more effectively and on a continuous basis. The acceptability of OTC drugs will improve once the awareness level is enhanced. When the knowledge of the traditional medicine is rooted in the culture, the knowledge about allopathic OTC drugs has to be disseminated by manufacturing company and ensure drastic reduction in the high information asymmetry existing today.

The OTC drug offering is incomplete with out empowering the public on its rational use through well planed strategic marketing initiative revolving around the aliment, the knowledge to diagnose and manage the same. In this empowerment process which can be considered as CSR, the objective should be prevention and holistic awareness creation leading to health and wellbeing than just offering the minimum needed information to use one’s products.

Thus by educating public (consumer) on how to manage common ailments and finally how to prevent them, the pharma companies can achieve its real goal of health for all and improve the quality of people’s life.

The social benefit at a national level will be lesser work load on general practitioners, lesser crowding in primary health centers (PHCs), pharmacists who are more empowered to guide and counsel patients and more confident public who are in a better position to take more informed choice of the best available solution to treat their common ailments and prevent the frequent occurrence of the same. This will increase productivity at work and every one in society can make superior contribution towards nation building as it strives to be a developed one.

\* Eric P. Brass (2001), New England Journal

\*\* Datamonitor

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